K131118
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510(k) Summary

MAY 16 2013

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 19, 2013
Submitter:	GE Healthcare, 9900 Innovation Dr. Wauwatosa, WI 53226
Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare Phone: 414-721-4214 Fax: 414-918-8275
Manufacturer:	GE Healthcare Austria GmbH & Co OG Tiefenbach 15 Zipf, Austria 4871
Device: Trade Name:	4D View
Common/Usual Name:	4D View
Classification Names: Product Code:	CFR 892.2050, LLZ Picture Archiving and Communication Systems
Predicate Device(s):	K101166 4D View K122327 GE Voluson E6/E8/E8ExpertE10 Diagnostic Ultrasound System
Device Description:	4D View is a standalone Software product, which can be installed on a Laptop/PC with Microsoft Windows 7, Windows 8 and as virtual machine with Windows 7 on MAC operating systems: Primary Operating Functions are: • Display and editing of 3D/4D data sets • Measurements on displayed image incl. derived calculations based on medical literature in the following applications: Abdominal, Obstetrics, Gynecology, Cardiology, Urology, Vascular, Neurology, Small Parts, Pediatrics, Musculo-Skeletal (Orthopedics). • Data storage (image, measurement and patient data) • Data transfer to and from remote systems (e.g. via DICOM) • Adding annotations to acquired image

Intended Use: Image Display of 3D/4D data sets for diagnostic purposes including measurements on displayed image.

Technology: The 4D View employs the same fundamental scientific technology as its predicate device(s).

Modification to 4D View: The Intended Use and Indications for use have not changed from the unmodified device. This modification introduces the ability for 4D View to work with additional GE Ultrasound features and data.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The 4D View and its applications comply with voluntary standards:

1. IEC62304, Medical device software - Software life cycle processes
2. ISO14971, Application of risk management to medical devices
3. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, 4D View, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the 4D View to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2013

GE Healthcare
% Mr. Bryan Behn
Regulatory Affairs Manager
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K131118
Trade/Device Name: 4D View
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 19, 2013
Received: April 24, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

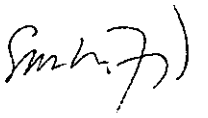
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K131118

Device Name: 4D View Software

Indications for Use:

Image Display of 3D/4D data sets for diagnostic purposes including measurements on displayed image.

Prescription Use_X___ AND/OR Over-The-Counter Use_N/A_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) Number K131118